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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/607,690	06/30/2003	Jonathan Scott Darling	990892-30	7686

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EXAMINER

SRIVASTAVA, KAILASH C

ART UNIT PAPER NUMBER

1655

DATE MAILED: 07/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/607,690	<b>Applicant(s)</b> DARLING ET AL.	
	<b>Examiner</b> Dr. Kailash C. Srivastava	<b>Art Unit</b> 1655	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.138(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 April 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-11 and 17-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 17-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>6.30.2003</u> . | 6) <input type="checkbox"/> Other: _____  |

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## **DETAILED ACTION**

1. Applicants' responsive amendment and remarks filed 17 April 2006 to Office Action mailed 31 March 2006 is acknowledged and entered. The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office action.
2. For the record to be complete and clear, Applicants are reminded that contrary to applicants' assertion, applicants' above-cited responsive amendment and remarks are not to the Office action mailed 31 March 2005, but rather to the Office Action mailed 31 March 2006.
3. In view of applicants' remarks and amendment 17 April 2006 to Office Action mailed 31 March 2006, Examiner hereby withdraws following objections/rejections:
  - i. Objection to Claims 1-11 and 17-20; and
  - ii. Rejection of Claims 1-11 and 17-20 under 35 U.S.C. §101;in the Office Action mailed 31 March 2006.

## **CLAIMS STATUS**

4. Claims 12-16 remain cancelled.
5. Claims 1, 1a), 2-11 and 17-20 have been amended.
6. Claims 1-11 and 17-20 are pending and are examined on merits.

## **Claim Objections**

7. In view of applicant's amendment filed 17 April 2006 to Office Action mailed 31 March 2006, following is a new objection to Claim 1a:
  - a. In Claim 1a at Line two, in between the words "to" and "pH" an --a -- should be inserted

## ***Claim Rejections - 35 U.S.C. § 112***

### ***Second Paragraph Rejections***

8. Claims 1-11 and 17-20 stand rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

- Phrase, "enzymatic digest medium" in Claims 1a, 1b, 2, 4-5 and 10 renders those claims unclear and therefore indefinite, because the metes and bounds for an "enzymatic digest medium" are not defined. Is this medium an enzyme in water or an enzyme in a buffer or an enzyme in any organic solvent or an enzyme that is dry or what? Appropriate correction/definition in the claim language regarding "enzymatic digest medium" is required.
- The recitation "protein solubles mixture" in Claims 1b-1e, 5-6 and 19 renders those claims unclear and therefore indefinite, because the metes and bounds for "protein solubles" are not defined. Are these solubilized proteins, i.e., hydrolysate or proteins that are soluble in some solvent or aqueous material or what? Applicants need to define the metes and bounds for the phrase, "protein solubles mixture".

All other claims depend directly from the rejected claims (e.g., Claim 1) and are, therefore, also rejected under 35 U.S.C. §112, second paragraph for the reasons set forth above.

9. In response to rejections under 35 U.S.C. § 112, 2<sup>nd</sup> paragraph to Claims 1-11 and 17-20 in regard to phrase, "enzymatic digest medium" made in the Office Action mailed 31 March 2006, applicants argue that definition for said phrase has been "clearly provided in the specification".

Applicants' arguments filed 17 April 2006 regarding the rejections to Claims 1-11 and 17-20 in the Office Action mailed 31 March 2006 have been fully and carefully considered but those arguments are not persuasive for the reasons of record at page 3 in the Office Action mailed 31 March 2006 and for the reasons discussed *infra*.

Applicants' definition of the phrase "enzymatic digest medium" as presented in the Claims filed on 19 December 2005 or the amended Claims filed 17 April 2006 do not define with precision and particularity the claimed invention in claims 1-11 and 17-20 under 35 U.S. C. §112, 2<sup>nd</sup> paragraph. Furthermore, applicants are reminded that the invention is the subject matter defined by the claims, and the limitations of the specification, clearly defined as they may be, are not read into the claims where no express statement of that limitation is provided /included in the claims (See, *In re Priest*, 199 USPQ 11). Applicants are also made aware that the limitations appearing in the specification will not be read into the claims, and interpreting what is meant by word/phrase in a claim is not to be confused with adding an extraneous limitation appearing in the specification, which is improper. (*Intervet Am., v. Kee-Vet Labs.*, 12 USPQ 2<sup>nd</sup> 1474, 1476 (Fed. Cir. 1989)).

10. Examiner suggests that the claims must be written according to the standard U.S. Patent Practice. Upon resolution of the above-stated issues under 35 U.S.C. §112, further searching and/or consideration may be required.

### **PRIOR ART**

11. The following prior art made of record and not relied upon is still considered pertinent to Applicants' disclosure.

- Emanuel, U.S. Patent 3,899,419, issued 12 August 1975;
- Freeman et al., U.S. Patent 4,473,589, issued 25 September 1984;
- Shih et al., U.S. Patent 4,959,311, issued 25 September 1990; and
- WO 86/04487 issued 14 August 1986.

### **CONCLUSION**

12. For the aforementioned reasons, no claims are allowed.

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Terry McKelvey, can be reached on (571)-272-0775 Monday through Friday 8:00 A.M. to 4:30 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for

unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). Alternatively, status inquiries should be directed to the receptionist whose telephone number is (703) 308-0196.

  
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Patent Examiner  
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July 9, 2006

  
RALPH GITOMER  
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